

REMARKS

In the Specification.

The title has been amended as suggested by the examiner.

In the Claims.

Claim 4 has been amended due to a typographical error.

35 USC 112

The Examiner states that the term "biodegradable" of claim 9 has no antecedent basis. Claim 9 has been amended to remove the term "biodegradable."

35 USC 103 Obviousness

Claims 1, and 3-20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Tuting & Albers in view of Roser et al and Volkin et al.

The examiner states on page 10, line 14, that "Given the benefits accrued by adapting the modifications taught by both, Roser et al and Volkin et al for improving and stabilizing the DNA pharmaceutical agent dosage form of Tuting & Albers, one of ordinary skill in the art would be motivated to make such modifications...." We respectfully disagree with this basis of rejection on the following grounds.

First, the Examiner says on page 12 last paragraph :

The argument that one of ordinary skill in the art would not have any reason to successfully combine the free radical scavengers and ion chelators used by Volkin et al in stabilizing DNA pharmaceutical agent for vaccine formulation that can be coated on to a bead for ballistic delivery (as taught by Tuting & Albers, in view of Roser et al), is not found to be persuasive because such stabilizing agents (as EDTA) have been successfully used and have been disclosed by Tuting & Albers (see page 35, coating DNA on gold particles, in particular), and can be coated on the bead using sugars glass as taught by Roser...

Respectfully, Applicants are confused by this reference. There is no mention on page 35 of Tuting & Albers the use of EDTA. Tuting & Albers does however, disclose the use of EDTA on pages 38 and 39 but only for the processes of resuspending the cells after transfection and washing the transfected cells after being placed in the magnetic separator. In both instances EDTA is not being used a stabilizing agent and furthermore is being used after the point at which the cells have been transfected with the DNA, so the use of EDTA at this stage cannot provide any stabilization of DNA in the particle as it is used in the present invention.

Further, the Examiner characterizes Roser on page 9, beginning on the first line, by saying

Roser et al disclose the existing problems in the powder formulations in the prior art that use dense core element such as gold or tungsten microparticles coated with DNA agent as delivery vehicles for ballistic administration (see Roser et al, column 2, last paragraph, in particular) that were largely unsuitable because of the irregularities in the particle size and shape of the available powders, and provide simple and economical solution and associated advantages of using solid dose drug delivery of defined size, shape, shape and density...

Roser also discloses in column 3 that the use of sugar glass is a better method for delivering DNA into the body due to the uneven particle size of the gold beads and the effect this has on penetrating the skin. Roser therefore teaches away from the use of gold beads as a delivery method, and therefore, even if it were obvious to combine the teachings of Roser and Tuting & Albers (with which Applicants respectfully disagree) the only conclusion that the skilled man would draw from this is that he should use the sugar glass method as disclosed by Roser and not in combination with gold beads.

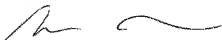
There is also no suggestion in Volkin that the use of the free radical scavengers and ion chelators would work to stabilize the DNA in addition to the sugar glass, and what is more, the skilled man would assume that the ability of the sugar glass to remain in the correct formulation so as to stabilize the DNA would be decreased by the addition of additional components.

The Examiner cites *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971) for the proposition that so long as it takes into account only knowledge which was within the level of ordinary skill at the time of the claimed invention was made, and does not include knowledge

gleaned only the the applicant's disclosure, such as reconstruction is proper. Applicants are in full accord with the Examiner. It is believed that Applicants' above arguments have convinced the Examiner that the level of ordinary skill at the time of filing was not high enough to have combined the teaching of Tuting & Albers, Roser and Volkin. On the contrary, the three references are incompatible to each other with the regard to the presently claimed invention.

It is believed that Applicants have presented convincing argument to traverse the obviousness argument. Re-examination and re-consideration are respectfully solicited. Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. If any additional fees or charges are required by this paper the Commissioner is hereby authorized to charge Deposit Account No. 19-2570, accordingly.

Respectfully submitted,



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